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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,236	08/29/2000	Jiangchun Xu	210121.427C18	9536

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EXAMINER	
SOUAYA, JEHANNE E	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/651,236	Xu et al.
Examiner	**Art Unit**
Jehanne Souaya	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 9, 2000* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) ~~1-63~~ 1-61, 63 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims ~~1-63~~ 1-61, 63 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4-10, 16, and 58-60, drawn to an isolated polynucleotide, a polynucleotide encoding a polypeptide, and a polynucleotide encoding a fusion protein, vectors and host cells comprising the polynucleotide, classified in class 536, subclass 23.1, and class 435, subclass 320.1 and 252.1.

II. Claims 1-3, 12, 13, 15, 61, and 63, drawn to an isolated polypeptide and a fusion protein comprising the polypeptide, classified in class 530, subclass 350.

III. Claims 11, 54, 55, and 57, drawn to an antibody, classified in class 530, subclass 387.1.

IV. Claims 48-53, drawn to a method for determining the presence of cancer and monitoring the progression of cancer in a patient using nucleic acid based assays, classified in class 435, subclass 6.

V. Claims 40-47, drawn to a method for determining the presence of cancer and monitoring the progression of cancer in a patient using polypeptide based assays, classified in class 435, subclass 7.1.

VI. Claims 17-22, 31, and 35-39, drawn to a pharmaceutical composition comprising, an immunogenic composition comprising, a method for inhibiting development of cancer by administering an effective amount of an immunogenic composition

comprising, methods of stimulating T cells by contacting T cells with, and a method for inhibiting the development of cancer comprising incubating CD4+ and/or CD8+ T cells with a polynucleotide sequence, classified in class 514, subclass 44.

VII. Claims 14, 17-22, and 31-39, drawn to a pharmaceutical composition comprising, an immunogenic composition comprising, a method for inhibiting development of cancer by administering an effective amount of an immunogenic composition comprising, methods for removing tumor cells from a biological sample comprising contacting the biological sample with T cells that react with a tumor protein comprising, methods of stimulating T cells by contacting T cells with, and a method for inhibiting the development of cancer comprising incubating CD4+ and/or CD8+ T cells with a polypeptide sequence, classified in class 514, subclass 2.

VI. Claims 17-22, 31, and 56, drawn to a pharmaceutical composition comprising, an immunogenic composition comprising, a method for inhibiting development of cancer by administering an effective amount of an immunogenic composition comprising, an antibody, classified in class 424, subclass 130.1.

VI. Claims 23-31 and 35-39, drawn to a pharmaceutical composition comprising, an immunogenic composition comprising, a method for inhibiting development of cancer by administering an effective amount of an immunogenic composition

comprising, methods of stimulating T cells by contacting T cells with, and a method for inhibiting the development of cancer comprising incubating CD4+ and/or CD8+ T cells with an antigen presenting cell comprising a polypeptide, classified in class 424, subclass 93.21.

Please note a claim 62 is missing from the specification.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I, II, and II are patentably distinct from each other because they are drawn to different products having different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide of group II is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the antibody of group III is also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The products of groups I-III can be used in materially different processes, for example the DNA of group I can be used in hybridization assays, the antibody of group III can be used in immunoassays, and the polypeptide of group II can be used to make a fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I, II, and III are patentably distinct from each other.

The inventions of groups I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of group I can be used to express proteins which is not required for the method of group IV.

The invention of group I is not related to the invention of group V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide of group I is not used in the method of detection using polypeptide based assays of group V.

The invention of group II is unrelated to the invention of group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of group II is not used in the method of detection using nucleic acid based assays of group IV.

The inventions of groups II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the polypeptide of group II can be used to make fusion proteins with enzymatic functions which are not required for the method of detection of group V.

The invention of group III is unrelated to the inventions of group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of group III are not used in the method of detection using nucleic acid based assays of group IV. The inventions have different modes of operation, different functions, and different effects.

The inventions of groups III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of group III can be used in immunoassays which are not required for the method of detection of group V (the compound that binds to the polypeptide can be a specific ligand for the polypeptide.

The inventions of groups IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of detection using nucleic acid based assays of group IV and the method

of detection using polypeptide based assays of group V have different modes of operation, different functions, and different effects. Each method requires different reagents, reaction conditions, and reaction parameters.

The methods and composition of Groups VI-IX are patentably distinct from each other as they are drawn to using or containing the following patentably distinct products, polypeptides, polynucleotides, antibodies, and antigen presenting cells which are structurally and functionally different from one another. The polynucleotide of group VI is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide of group VII is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While antibodies of group VIII are also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The antigen presenting cells of group IX differ structurally and functionally from the polynucleotides, polypeptides, and antibodies of groups VI-VIII.

The inventions of groups VI-IX are patentably distinct from the inventions of groups I-V. The methods of stimulating T cells, the pharmaceutical compositions, the immunogenic compositions comprising immunostimulants, a method for stimulating an immune response and a method for inhibiting cancer use or are comprised of products that are patentably distinct from the products of groups I-III and are not used in the methods of groups IV or V. The polynucleotides, polypeptides, antibodies, and antigen presenting cells of groups VI -IX are

patentably distinct from the products of groups I-III as the products of groups VI-IX are contained in compositions comprising immunostimulants or compositions for use with therapeutic methods. The products of group VI-IX are also used in materially different processes than the products of groups I-III. For instance the products of groups VI-IX can be used in and are modified for use in methods of stimulating T cells, methods of stimulating an immune response, or methods for inhibiting cancer. The products of groups VI-IX, which are used in methods of immunology and therapy are not used in the methods of detection of groups IV and V. Further, the methods of immunology and therapy of groups VI-IX do not require use with or are obvious over the methods of detecting or monitoring the progression of cancer of groups IV or V.

3. Upon election of an invention from groups I-IX above, applicant must further elect a patentably distinct sequence. This is NOT an election of species. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141.

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more

independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-IX, restriction for examination purposes as indicated is proper. Further, the search required for one sequence is not required for the search of a different sequence.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1655
12/14/01